

**REMARKS**

Entry of the foregoing amendment and reconsideration of the application, pursuant to and consistent with the Rules of Practice in Patent Cases, in light of the remarks which follow, is respectfully requested. The present RCE application is a continuation of Application No. 10/079,071, filed February 20, 2002. The proposed amendments to the claims filed September 7, 2005, have not been entered in the present application. By the present amendment, claims 1, 7, 12, 17, 22, and 26 have been amended, so that upon entry of the present amendment claims 1-9 and 12-34 will be pending.

The claims have been amended to more particularly point out the relationship between and distinctly claim the various "filler" components of the claimed composition. These amendments make it clear that the composite filler particles are distinct from the other components (including other filler materials) of the claimed composition. The composite filler particles are prepared prior to combination with other components of the composition and are distinct from any filler material added to the composition that is not part of the composite filler particles. The composite filler comprises a polymerized mixture of organic binder and inorganic filler which has been made into particles.

The composition includes organic binder, polymerization initiator and the composite filler particles. The composition is open to the addition of further materials, such as other filler material, provided that the composition is limited to at most 10% by weight of composite filler particles having a size of  $< 10 \mu\text{m}$ . See claims 12-26 and 31. Thus, the composition of amended claim 1 remains open to the addition of non-composite fillers which would not be restricted by the 10 wt.-% limitation. This is supported by the disclosure at page 11, lines 8-20 of the present specification. Further, the composite filler particles remain open to the addition of further materials, see claims 3-9, as supported by pages 8-9 of the specification.

In the parent application, claims 1-9 and 12-34 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,356,951 to Yearn et al. ("Yearn") in view of WO 00/61703 to Blackwell et al. ("Blackwell"), DE 3502594 A1 to Michl et al. ("Michl"), U.S. Patent No. 4,503,169 to Randklev ("Randklev"), and U.S. Patent No. 4,668,712 to Hino et al. ("Hino"). The this rejection is traversed for at least the following reasons.

The present invention relates to a composition useful as a dental material containing a particulate composite filler comprising a polymerized mixture of organic binder and inorganic filler, having an average particle size of 20 to 50  $\mu\text{m}$  and containing at most 10 wt.-% of particles with a size of  $< 10 \mu\text{m}$ . The present invention provides polymerizable compositions with low polymerization shrinkage, transparency and polishability. The compositions achieve these desired characteristics through the use of a novel filler based on a particulate composite material.

As described in the present specification, a suitable particulate composite filler can be prepared, for example, by mixing an organic binder and filler, a polymerization initiator, curing, and then grinding the mixture (page 5, last paragraph). As is known in the art, during normal grinding of a composite material, a considerable amount of fine particulate material (i.e., having a particle size of  $< 10 \mu\text{m}$ ) is formed (page 6, second paragraph). Example 1 and Figure 1 of the present specification show, for example, that grinding of such a composite material to an average particle size of 21  $\mu\text{m}$  resulted in the formation of composite particles having a size of less than 10  $\mu\text{m}$  in a proportion of about 40 percent.

Applicants have surprisingly found that removing this fine particulate composite filler from the composition (i.e., by restricting the amount of composite filler particles having a grain size of less than 10  $\mu\text{m}$  to 10 wt.-% or less) can reduce the degree of polymerization shrinkage of the composition. Examples 2 and 3 of the present invention, for example, show that the polymerization shrinkage of a polymerizable composition was reduced from 1.9% to 1.6% by removing the fine particulate composite filler.

Yearn do not disclose dental materials or fillers according to the composition of the present invention. Yearn teach the use of a filler having three components. One of these components, component (b-i), is a composite filler. However, contrary to the present invention, this composite filler is made of substantial amounts of particles having a size of less than 10  $\mu\text{m}$ . In the examples Yearn use composite materials having a mean particle diameter within the range of 8  $\mu\text{m}$  (column 5, line 67) to 15  $\mu\text{m}$  (column 5, lines 57 to 58), i.e. filler having a mean particles size which is below 20  $\mu\text{m}$ . All materials used in the examples are obtained by curing and pulverizing a mixture of monomer and glass powder (column 5, lines 29 to 67). It was shown by the present inventors that common pulverization of composite materials results in the formation of a substantial amount of fine particulate material. In Example 1 of the present application it is shown that grinding of a composite

material to an average grain size of 21  $\mu\text{m}$  results in the formation of about 40% of composite particles having a size  $< 10 \mu\text{m}$ . Therefore, it is evident that the materials disclosed by Yearn must contain a significant portion of composite filler particles having a size of less than 10  $\mu\text{m}$ .

Blackwell discloses polymerizable compositions having filler combinations with a defined size distribution and size relationship (page 3, last paragraph). According to Blackwell a composite paste containing ground glass particles with a particle size distribution of about 0.05 to 1  $\mu\text{m}$  together with small amounts of siliceous filler with a particle size distribution between about 0.01 and 0.1  $\mu\text{m}$  (page 4, lines 1 to 4) is mixed with an additional fraction of filler chosen such that the mean particle size of this additional filler is at least about 20 times the size of the largest filler in the paste (page 4, lines 15 to 17). Specifically disclosed on page 4, lines 21-23 is an additional filler having a mean particle size of at least about 20  $\mu\text{m}$  with no particles larger than 25  $\mu\text{m}$  or smaller than 15  $\mu\text{m}$ . The second filler does not render obvious the particulate composite filler of the present invention as it would not have been obvious to substitute this second filler for the composite filler of Yearn.

It should be noted that Blackwell teaches the use of milled glass as the second filler component (page 5, lines 1. to 2). According to Example 2 the additional filler is made by milling glass frit with a particle size of 2 to 5  $\mu\text{m}$  to obtain powder with a particle size ranging from about 1  $\mu\text{m}$  to 1 mm and having a mean particle size of about 50  $\mu\text{m}$  (paragraph bridging pages 5 and 6). This powder is sieved to obtain Fraction A having a particle range between 100 to 250  $\mu\text{m}$  and Fraction B having a particle size range of 48 to 85  $\mu\text{m}$  (page 6, first paragraph). It is evident that the average particle size of both fractions is outside the claimed range of 20 to 50  $\mu\text{m}$  of the composite filler.

Blackwell does not teach the use of composite materials as the additional filler component. Composite fillers are typically prepared by mixing organic binder, filler and polymerization initiator, curing and grinding the mixture (see page 5, last paragraph of the present application). Milled glass is not a composite filler as required by the present claims.

Yearn teach curable compositions which contain both a composite filler (b-i) and glass powder (b-ii). Thus, if a skilled person had combined Yearn and Blackwell he would not have replaced the composite filler component (b-i) with the glass powder of Blackwell in order to obtain a material having two glass powder fractions, but he would instead have replaced the glass powder (b-ii) with the glass powder of Blackwell. As a result

he would have obtained a material including composite filler (b-i), which has substantial amounts of fine particulate composite filler as explained above, and the glass powder of Blackwell. If the skilled person, contrary to the teaching of Yearn had replaced composite filler (b-i) with the glass powder of Blackwell he would have obtained a material having two different glass powders but no particulate composite filler, as required by the present invention. Therefore, a combination of the teachings of Yearn and Blackwell would not render the present invention obvious.

The composition of Example 3 of the present invention resembles the compositions of Yearn in that it contains fine composite filler particles which were not removed. It follows that the polymerization shrinkage of the claimed materials of the present invention is also improved with regard to the teachings of Yearn.

If a skilled person had added coarse particulate material according to Blackwell to the compositions of Yearn he would not have achieved compositions for use in dental material. According to the present invention a composition including 82% filler (page 17, lines 1 to 9; 2.5 wt.-% of 12.5 wt.-% layered silicate dispersed in monomer mixture corresponds to 0.3% solid materials in the final composite) shows a shrinkage upon polymerization of 1.6% (page 16, line 3). According to the table at page 14 of Blackwell, 86% filler is needed to achieve the same volume shrinkage of 1.6% (composition number 3). Thus, a significantly higher amount of filler is needed in accordance with the teachings of Blackwell.

According to this table, 86% of filler results in a volume shrinkage of 1.6%, 87% filler of 1.5% and 88% filler of 1.4%, respectively. Thus, raising the amount of filler by 1% reduces the shrinkage by about 0.1%. It can thus be estimated that a composition including 82% of filler as in Example 2 of the present application will have a volume shrinkage of about 1.9 to 2.0%. Thus, the polymerization shrinkage of the compositions according to Blackwell are comparable to the shrinkage of the material which has been used as the comparative material in Example 3 of the present application, i.e., it is significantly higher than the shrinkage of materials including the composite filler particles of the present invention. Consequently, the addition of coarse particulate filler as suggested by Blackwell does not result in the same improvement as that achieved by the present invention.

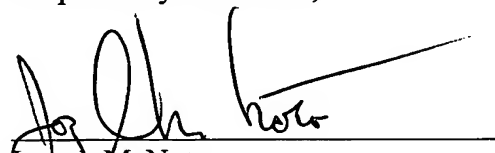
Moreover, compositions of the present invention may contain additional filler having a particle size of  $<10\text{ }\mu\text{m}$  other than the particulate composite filler of the present

invention. In fact, such fillers are used in the examples of the present application. The compositions of the present invention include a particulate composite filler as defined above as an important component. As is evident from the prior art discussed in the introductory section of the application, dental materials having only inorganic filler were not satisfactory. Moreover, as has been discussed above, the use of composite filler particles according to the prior art is also not satisfactory because it results in a high polymerization shrinkage. In addition, the prior art fine particulate composite filler significantly raises the viscosity of the composition which makes it difficult if not impossible to incorporate further fillers into the composition. It has been found by the present inventors that these disadvantages can be overcome by removing the fine particulate composite filler from the composition. By doing this, other fillers, including non-composite fillers having a particle size of  $<10\text{ }\mu\text{m}$ , can be incorporated into the composition which allows further improvements of these compositions.

Accordingly, even if one were to combine the teachings of Yearn and Blackwell, the claimed invention is not achieved. The other secondary references cited by the Office, are said to disclose various dependent features of applicants' claims, and none of the references teaches, suggests, or recognizes the benefit to be obtained by reducing the proportion of fine particulate composite filler in the composition. As none of the cited art, alone, or in combination, discloses the claimed invention, withdrawal of the record rejection is respectfully requested.

In view of all of the foregoing, applicants submit that this case is in condition for allowance and such allowance is earnestly solicited.

Respectfully submitted,

  
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